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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/756,169	WENRICH, MARSHALL S.	
	Examiner	Art Unit	
	WILLIAM H. BEISNER	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2008 and 21 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/21/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/2/2008 has been entered.

Information Disclosure Statement

2. The information disclosure statement filed 1/21/2009 has been considered and made of record.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-3, 10, 21-25 and 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alford et al.(WO 03/024214 or US 2003/0054540 or US 6,677150) in view of McKelvey et al.(EP 0 376 763) and Bacchi et al.(US 5,285,657).

The references of Alford et al. disclose a portable apparatus (See Figures 1 and 2) for maintaining an ex vivo organ in a viable condition for transplantation. The apparatus includes an organ container (8) including an interior space for receiving an organ to be transported; a bubble remover (11) having a headspace and venting valve (12); an oxygenator (21) having a chamber for receiving perfusion fluid, a gas space for receiving oxygen, and a gas exchange interface allowing gas exchange between the chamber and the gas space (See paragraphs [0049]-[0050] of '540); a perfusion loop (See Figure 1) including the container inner space, the bubble remover headspace and the oxygenator interconnect to provide fluid circulation; a pump (4) configured for circulating a perfusion fluid through the perfusion loop; and an outer container (1,2) sized and configured to contain the organ container (8), the bubble remover (11), the oxgyenator (21), the perfusion loop, the pump (4) and a supply of oxygen (17) in an operative position (See Figure 2).

Claim 1 differs by reciting that the perfusion loop including the organ container, bubble remover and oxygenator are movable into and out of the outer container and into and out of an operative relationship with the pump while the perfusion loop remained closed.

The reference of McKelvey et al. discloses that it is known in the organ perfusion art to provide a closed perfusion loop in a sterile manner such that it can be removed as a unit (31) from an outer container (30).

The reference of Bacchi et al. discloses that it is known in the organ perfusion art to provide a removable circuit (60) with allows the circuit to be movable into and out of an outer container (10) and into and out of an operative relationship with the pump (31) while the circuit remains closed.

In view of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the construction of the system of the primary references of Alford et al. such that the perfusion loop can be removed from the outer container as suggested by the reference of McKelvey et al. and allowing the loop to be removed from an operative relationship with the pump as suggested by the reference of Bacchi et al. for the known and expected result of allowing the loop to be moved between containers and/or locations while remaining in a sterile condition and while allowing the pump to be reused and/or remain with the outer container.

Claim 1 also differs by reciting that the components of the perfusion loop are permanently connected or bonded.

However, the reference of Alford et al. discloses that the tubing in the system can be connected to the barbs on the components using solvent or U.V. bonding (See column 5. lines 50-61).

As a result, use of solvent or U.V. bonding on the components of the modified primary reference as discussed above would result in the components of the perfusion loop being permanently joined together as required in claim 1.

With respect to claim 2, the reference of Alford et al. discloses the use of tubing (19) to connect the elements of the device and the reference discloses the use of peristaltic pump (24).

With respect to claim 3, the reference discloses the use of temperature regulator (6).

With respect to claim 10, the temperature regulator (6) is in heat-exchange contact with the organ container (8) (See Figure 2).

With respect to claims 21, 25, 31 and 32, any of the elements listed above are considered to be capable of being disposed of after a single use. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 22, the reference of Alford et al. discloses the use of tubing (19) to connect the elements of the device. Also, any of the elements listed above are considered to be capable of being disposed of after a single use. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 23, the reference of Alford et al. discloses the use of pump (24).

With respect to claim 24, any of the components of the device can be disposed of or reused. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 30, the reference of Alford et al. discloses the use of a cover (9) including an adaptor (7) and quick connect-disconnect coupling (5).

With respect to claim 33, the organ container (8), bubble remover (11) and oxygen container (21) are mechanically joined (See Figures 1 and 2).

With respect to claim 34, the references of McKelvey et al. and Bacchi et al. both disclose the use of a support member (See element 31 of McKelvey et al. and element 600 of Bacchi et al.). As a result, it would have been obvious to one of ordinary skill in the art to provide the system of modified primary reference with a support structure for the known and expected result of facilitating the removal of the loop from the outer container.

6. Claims 3-9 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alford et al.(WO 03/024214 or US 2003/0054540 or US 6,677,150) in view of McKelvey et al.(EP 0 376 763) and Bacchi et al.(US 5,285,657) taken further in view of Olympus (JP-01-261301).

The combination of the references of Alford et al., McKelvey et al. and Bacchi et al. has been discussed above.

Claims 3-9 differ by specifying the use of a specific temperature regulation system that includes heat exchange fluids, tubes and a Peltier device to regulate the temperature of the perfusion loop.

The reference of Olympus discloses that it is known in the art of organ perfusion to employ a coolant (19) in heat exchange communication with the perfusion loop and to employ a Peltier device (15).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the temperature control taught by the reference of Olympus in the system of the primary reference for the known and expected result of providing an art recognized means for providing temperature control of the perfusion loop system.

With respect to claim 4, if the tubes of the perfusion loop do not meet this claim, it would have been obvious to one of ordinary skill in the art to provide heat exchange tubes in the system for the known and expected result of increasing the surface area for heat exchange between the perfusion fluid and heat exchange fluid.

With respect to claims 5 and 6, the Peltier device (15) is capable of heating or cooling the perfusion fluid.

With respect to claims 7-9, the system of Olympus discloses the use of a temperature controller (20) which is capable of being programmed as indicated in the claims. Also it would have been well within the purview of one having ordinary skill in the art to employ the device for cooling during storage and/or transport of the organ and warming of the organ prior to implantation.

With respect to claim 35, the reference of Olympus discloses the use of a coolant and cooling vessel (See the English language abstract).

7. Claims 11-20 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alford et al.(WO 03/024214 or US 2003/0054540 or US 6,677,150) in view of McKelvey et al.(EP 0 376 763) and Bacchi et al.(US 5,285,657) taken further in view of Owen et al.(US 6,673,594).

The combination of the references of Alford et al., McKelvey et al. and Bacchi et al. has been discussed above.

Claims 11 and 12 differ by reciting that the device includes a reservoir with a temperature regulator.

The reference of Owen et al. discloses that it is conventional in the art of organ perfusion to provide the perfusion system with a reservoir (10) that includes a temperature regulator (30a).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system of the primary reference with a reservoir system as suggested by the reference of Owen et al. for the known and expected result of providing a source of additional perfusion fluid that can be added to the perfusion loop and maintained at the required temperature conditions.

Claims 13-16 differ by reciting that the device includes a processor for controlling the perfusion conditions within the device.

The reference of Owen et al. discloses that it is conventional in the art of organ perfusion to provide the perfusion device with a processor that can be programmed by the user (See column 13, lines 23-41; and column 15, lines 24-44).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system of the primary reference with a processor for the known and expected result of automating the operation of the device.

Claims 17-20 differ by reciting that the device includes a processor controlled venting system.

The reference of Owen et al. discloses that it is conventional in the art of organ perfusion to provide the perfusion device with an air venting system that operates in conjunction with a bubble detection and removal system (See column 14, lines 34-61; column 18, lines 11-21).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the device of the primary reference with the bubble detection, removal and gas venting

system suggested by the reference of Owen et al. for the known and expected result of automating the removal of gas or bubbles from the perfusion loop.

Claims 26-29 differ by reciting that the device includes a radio frequency identification tag installed on the organ container and associated reader wherein the tag is used to program the control processor.

The reference of Owen et al. discloses that the use of a radio tag and reader are known in the art of organ perfusion (See column 13, lines 23-41).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the device of the primary reference with a radio tag system suggested by Owen et al. for the known and expected result of providing a means recognized in the art for allowing the organ to be remotely monitored and/or data to be transferred for further use and/or control.

Response to Arguments

8. With respect to the rejection of Claims 1-3, 10, 21-25 and 30-34 under 35 U.S.C. 103(a) as being unpatentable over Alford et al.(WO 03/024214 or US 2003/0054540 or US 6,677150) in view of McKelvey et al.(EP 0 376 763) and Bacchi et al.(US 5,285,657); Claims 3-9 and 35 under 35 U.S.C. 103(a) as being unpatentable over Alford et al.(WO 03/024214 or US 2003/0054540 or US 6,677,150) in view of McKelvey et al.(EP 0 376 763) and Bacchi et al.(US 5,285,657) taken further in view of Olympus (JP-01-261301); and Claims 11-20 and 26-29 under 35 U.S.C. 103(a) as being unpatentable over Alford et al.(WO 03/024214 or US 2003/0054540 or US 6,677,150) in view of McKelvey et al.(EP 0 376 763) and Bacchi et al.(US 5,285,657) taken further in view of Owen et al.(US 6,673,594), Applicant argues that the rejection is

improper because *"The cited prior art references all fail to show "portable apparatus for maintaining an ex vivo organ in a viable condition for transplantation," in which "the organ container, the bubble remover, the oxygenator, and the perfusion loop are permanently joined together in fluid-conducting relation to define a single sterile, closed unit," as claim 1 recites and the remaining claims incorporate by reference back to claim 1."* (See pages 9-12 of the response dated 9/2/2008).

Applicant's comments are not found to be persuasive for the following reasons:

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case it is the combination of the reference that suggest the claimed invention. In particular, Applicant stresses that the primary reference of Alford et al. discloses the use of quick disconnect connections and therefore does not disclose a perfusion loop that is permanently joined together. However, as recited in the prior art rejection above, the reference of Alford et al. also discloses that solvent or U.V. bonding can be used to join the tubes to the system components (See column 5, lines 50-61). In view of this teaching and the teachings of the additional references, the Examiner is of the position that the structure of the instant claims is met by the combination of the references set forth above in the 35 USC 103 rejections above.

9. With respect to the obviousness-type double patenting rejections of record over U.S. Patent No. 6,677,150, the rejections have been withdrawn in view of the amendments made to claim 1 in the response filed 9/2/2008

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner
Art Unit 1797

WHB